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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,935	08/27/2003	James M. Brugger	53951-102	8073

21890 7590 12/06/2005
PROSKAUER ROSE LLP
PATENT DEPARTMENT
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EXAMINER

KIM, SUN U

ART UNIT PAPER NUMBER

1723

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,935

Applicant(s)

BRUGGER ET AL.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14 and 30-43, drawn to a kit or fluid circuit, classified in class 210, subclass 257.2.
- II. Claims 15-29, drawn to a method for performing renal replacement therapy, classified in class 604, subclass 4.01.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus such as a heater installed on dialysis circuit.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I (claims 1-14): a sterilized fluid management kit with blood circuit entirely sealed.

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Species II (claims 30-43): a fluid circuit or dialysis circuit with hermetic seal

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there is no generic claim.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1 (claims 15-23): a method for performing renal replacement therapy comprising the step of recirculating sterile fluid through the reservoir during a first stage of priming to permit gas to be purged from the sterile fluid and prime a first portion of the fluid circuit.

Species 2 (claims 24-29): a method for performing renal replacement therapy comprising the step of initiating a step of priming the fluid circuit with the filtered replacement fluid responsively to a signal indicating one of a passage of an interval of time, a mass of filtered replacement fluid, and a mass of unfiltered replacement fluid.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there is no generic claim.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. During a telephone conversation with Mr. Mark Catan on 11/30/05 a provisional election was made without traverse to prosecute the invention of Group I, Species 2, claims 30-43.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Mr. Catan acknowledged that the dependency of claims 31-39 and claims 41-43 should be changed as follows:

Claim 31 depends on claim 30.

Claim 32 depends on claim 31.

Claim 33 depends on claim 30.

Claim 34 depends on claim 33.

Claim 35 depends on claim 34.

Claim 36 depends on claim 30.

Claim 37 depends on claim 36.

Claim 38 depends on claim 30.

Claim 39 depends on claim 38.

Claim 41 depends on claim 40.

Claim 42 depends on claim 40.

Claim 43 depends on claim 40.

For examination purposes, above dependency of claims 31-39 and 41-43 are assumed and Mr.

Catan will make above corrections in response to this office action.

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6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The disclosure is objected to because of the following informalities:

Regarding the claiming the benefit of priority to US Pat. Application No. 09/905,246, the following language is suggested on page 1: "The present application is a continuation-in-part of US Patent Application No. 09/905,246, filed July 12, 2001, now US Patent No. 6,649,063."

Page 8 of the specification is missing pending application number filed on 3/20/2003 which is incorporated by reference.

Appropriate correction is required.

8. Claims 30-31, 39, 40 and 42 are objected to because of the following informalities: First occurrence of "having" on line 7 of claim 30 should be deleted. "said replacement fluid circuit is connected to said blood circuit by said replacement fluid circuit" on lines 2-3 of claim 31 needs clarification as to whether it's a replacement fluid container connected to the blood circuit. "said replacement fluid replacement fluid circuit" on line 7 of claim 31 should be changed to "said replacement fluid container and said replacement fluid circuit". "5 l." on line 2 of claim 39 should be corrected to "5 liters". "dilayzer" on line 5 of claim 40 should be corrected to "dialyzer". "said dialysis side" on line 3 of claim 42 should be corrected to "said dialysate side". Appropriate correction is required.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 30-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 is indefinite for failing to particularly point out whether a port is provided on a non-blood side of a dialyzer. Recitations of "said access line" on line 3 of claim 37, "said recirculating flow" on line 5 of claim 38, "said filter" on line 7 and "said replacement filter container" on line 8 of claim 40 lack a positive antecedent basis. Claim 40 is indefinite for failing to particularly point out what separates dialysate side from blood side.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 40 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Truitt et al (US Pat. No. 5,776,345). Truitt et al teach a fluid circuit comprising a dialyzer (40) having a connection connectable to a dialyzer (40) on one side, a blood circuit (38) on the other side is connected to a replacement fluid container (68) via line (70) wherein the replacement fluid container (68) and the line (70) inherently hermetically sealed (see figures 1-2; col. 3, line 55 – col. 4, line 40; col. 5, lines 26-41; col. 6, lines 21-26; col. 11, lines 34-52). Line (70) has a pump (66) (see figure 2). Claim 40 does not positively claim a dialyzer. Recitations of "a blood

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circuit” and “a replacement fluid container” in claim 40 and “venous and arterial lines” are an intended use of the circuit, the container and lines and are not given patentable weight for its intended use. Furthermore, the recitation of “whereby dialysate may be sterile filtered by passing from said dialysate side to said blood side of said dialyzer and stored in said replacement fluid container for use in treatment at which time said dialyzer is free for use for dialysis” is an intended use and are not given patentable weight. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

13. Claims 40-41 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Burbank et al (US Pat. No. 6,582,385). Burbank et al teach a fluid circuit comprising a hemofilter (182) having a connection (194) connectable to a hemofilter (182) on one side, the circuit (12, 28, 190) on the other side is connected to a fluid container (170) via lines (190, 192) wherein the container (170) and lines are pre-sterilized and inherently hermetically sealed (see figures 6 and 11; col. 15, line 1 – col. 16, line 44). Line (192) is a claimed line having a pumping portion since fluid is pumped out of the container (170) (see figure 7). Claim 40 does not positively claim a dialyzer. Recitations of “a blood circuit” and “a replacement fluid container” in claim 40 and “venous and arterial lines” are an intended use of the circuit, the container and lines and are not given patentable weight for its intended use. Furthermore, the recitation of “whereby dialysate may be sterile filtered by passing from said dialysate side to said blood side of said dialyzer and stored in said replacement fluid container for use in treatment at which time said dialyzer is free for use for dialysis” is an intended use and are not given patentable weight. It has been held that

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a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Truitt et al as applied to claim 40 above, and further in view of Polaschegg (US Pat. No. 6,280,632). Truitt et al teach a fluid circuit including a dialysis circuit (74) (see figure 1; col. 5, lines 42-56). Claim 42 essentially differs from the apparatus of Truitt et al in reciting a balancing circuit. Polaschegg teaches that a balancing system (100) is used in the hemodialysis circuit to ensure that the amounts of dialysis fluid flow at the inlet and outlet of the dialyzer are equal (see figure 1; col. 5, lines 8-25). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the apparatus of Truitt et al to incorporate a balancing circuit for dialysis fluid to ensure equal amount of dialysis fluid flow at the inlet and outlet of the dialyzer for effective hemodialysis treatment.

16. Claims 30-39 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

17. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record teaches or suggests the fluid circuit of claim 30 comprising a blood filter or dialyzer with a blood circuit and a replacement fluid connected to the container with a

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replacement fluid circuit connected to the blood circuit for diluting blood, the blood circuit communicating with a blood side of said blood filter or dialyzer having at least one patient access port connected to the replacement fluid container to define a recirculation path, a port on a non-blood side of the filter or dialyzer connectable to a source of replacement fluid, the recirculating path being entirely hermetically isolated from an outside of the fluid circuit except by a flow path through a membrane of the filter or dialyzer from the non-blood side to the blood side such that replacement fluid may be added to the replacement fluid container through the filter or dialyzer membrane and stored therein and a flow through the recirculating path may be established without making any connections or disconnections breaking the hermetic seal.

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat. No. 6,132,616 and 6,136,201 teaches filtering dialysate through membrane. US Pat. No. 6,187,207 and 5,808,181 and US 2005/0209547 teach apparatuses for preparing substitution or infusion fluid. WO 98/16269 teaches a replacement fluid line with a filter and a pump.


19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


John Kim
Primary Examiner
Art Unit 1723

J. Kim
December 1, 2005